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REMARKS

Claims 14-22 and 24-32 are pending herein, where claims 14-22 stand rejected under 35 U.S.C. §112, first paragraph, and claims 24-32 are new. The subject matter of claim 24 finds basis in the specification on page 28, line 13 to page 30, line 8, and claims 25-32 find basis in claims 2-9 as originally filed. Thus, no new matter has been added.

Claims 14-23 were rejected under 35 U.S.C. §112, first paragraph, as the claimed biological material allegedly is not publicly available. The rejection is moot in view of the Declaration by Mr. Mihara, which was requested in the Office action and is attached herewith. The Mihara Declaration states that certain deposits described on page 16 of the specification were made pursuant to the Budapest Treaty, that restrictions on public availability will be removed upon grant of a U.S. patent, and deposited materials will be replaced if the need should arise during the term of the deposit. Hence, Applicant respectfully requests that the rejection be withdrawn in view of the Mihara Declaration.

Also, claims 14-23 were rejected under 35 U.S.C. §112, first paragraph, because the specification enables specific monoclonal anti-human IL-6 receptor antibody (PM-1 and MR16-1) as therapeutic agents for diseases involving IL-6, but allegedly does not enable a method of treating multiple sclerosis. Applicant respectfully traverses the rejection.

Claim 24 is directed to a method for suppressing a sensitized T-cell by administering an anti IL-6 receptor antibody to a subject. The specification demonstrates that sensitized T-cells can be suppressed by administering such an antibody to C57BL/6 mice sensitized to *Mycobacterium butyricum*, as a one time administration of the antibody inhibited an immune reaction in a dose dependent manner (page 29, line 26 to page 30, line 8).

The Court of Appeals for the Federal Circuit has stated that such *in vivo* evidence is sufficient to establish the asserted usefulness and utility of an invention in *In re Brana*, 34 USPQ.2d 1436 (Fed. Cir. 1995). The court, citing *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971), stated that subject matter sought to be patented *must* be taken as being in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of statements in the specification that are relied upon for enabling support. Furthermore, the court stated that proof of a pharmaceutical property by statistically significant tests with standard experimental animals is sufficient to establish usefulness and utility, and that human testing is not required under Title 35 of the U.S. Code.

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Hence, the *in vivo* evidence provided by the specification establishes the utility and usefulness of the subject matter of claims 24-32, because it demonstrates that sensitized T-cells may be suppressed by administering an antibody to standard experimental animals. Furthermore, the studies are statistically significant as Figure 1 denotes error bars and statistical p values. Because no basis was set forth in the Office action for doubting this evidence of enablement, it is respectfully requested that claims 24-32 be allowed.

Moreover, the evidence that anti IL-6 receptor antibodies can be used to suppress sensitized T-cells in a subject also establishes the utility and usefulness of such antibodies in treatments of autoimmune disorders, specific examples of which are set forth in claim 14. Hence, it follows that the *in vivo* evidence set forth in the specification enables the subject matter of claims 14-22 in view of the court's position in *In re Brana*, and it is respectfully requested that the rejection of these claims be withdrawn.

Conclusion

Having addressed all the rejections, the application is believed to be in condition for allowance and a notice to that effect is respectfully requested.

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In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 350292000800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: June 7, 2001

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